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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

MAILED

Application Number: 09/866,030
Filing Date: May 25, 2001
Appellant(s): BHULLAR ET AL.

JUN 18 2007
GROUP 1700

Jill Woodburn
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/18/06 appealing from the Office action mailed 11/18/05.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,120,420

Nankai et al.

6-1992

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 10-15, 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are pointed out individually below.

Claim 24: "a support having first and second ends" it is unclear to define an end on a support that has 6 sides (flat support: top side, bottom side, left side, right side, upper surface, lower surface)

Claim 24: "and electrode array", it is unclear to define two pair of electrodes and call it an array.

Claim 24: "a spacer having individual members" is unclear. Claim 2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers.

Claim 24: "a cover cooperating with support to define a capillary channel extending between the individual members" The cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this.

Claim 24: "the channel having opposite ends" It is unclear and indefinite to claim a channel having opposite ends. Where does a channel end on the support?

Claim 24: "a concave inlet extending from the first end of the support and being positioned between opposite ends of the channel" It is unclear and indefinite to claim a concave inlet extending from a first end, what first end? Where on the support? The applicant needs to define the positioning and orientation of the inlet with respect to the channel that is defined by the support, cover and two spacers. The inlet is the channel? How is the inlet positioned between opposite ends? None of the figures show this.

Claim 24: "each electrode array being positioned in the channel adjacent to one of the opposing ends" What opposing ends? Adjacent to what? The electrode arrays are just two electrodes connected to each other to make a couple or pair of electrodes not an array.

Claim 25: "a support having first edge" It is unclear to define an edge on a support that has 6 sides (flat support: top side, bottom side, left side, right side, upper surface, lower surface).

Claim 25: "first and second electrode sets positioned on the support spaced apart from one another" Where on the support and what orientation are the electrodes related to each other.

Claim 25: "a spacer having individual members" is unclear. Claim 2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers.

Claim 25: "a cover having a second edge and extending across the first and second electrode sets," A cover has multiple edges, like a substrate defined above. It is unclear and indefinite to claim an edge on a cover. It is more than likely that the edge is not extended across the first and second electrode, it would be a plane of the cover and not an edge.

Claim 25: "the cover cooperating with support to define a generally linear capillary channel extending between the individual members" The cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this. A generally linear channel is unclear and indefinite.

Claim 25: "the channel having opposing first and second ends and an inlet aligned with the first edge of the support and the second edge of the cover" How does a channel have opposing first and second ends if it is not a totally closed channel,

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sounds more like a chamber, it is unclear and indefinite. First edge of the support and the second edge of the cover is unclear and indefinite, where are the spacers in this orientation?

Claim 25: "between the ends of the channel" What is this referring to?

Claim 25: "and between the first and second electrode sets" again what is this referring to, it is unclear and indefinite.

The biosensor needs to show communication between each object in a clear and concise manner in which one of ordinary skill in the art would be able to have a clear understanding of invention.

Claim 26 has the same problems as mentioned in claim 24 and claim 25. It is entirely unclear as a whole.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **6, 10-15, 21-26** are rejected under 35 U.S.C. 102(b) as being anticipated by Nankai (USPN 5,120,420).

Nankai teaches a biosensor that comprises a support substrate (1), electrodes positioned on the support substrate (2,3,3') and electrode system (4,5,5'), an insulating layer (6), a reaction layer (14) composed of an enzyme and an electron acceptor and

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being provided thereon with a space (8, channel) defined by a spacer (7) with members (fig.4 U shaped), an a cover (9). When the support substrate, spacer and members, and cover are sandwiched together a channel (8) is formed (fig. 4-6). When a biological sample solution is brought into contact with the inlet (10) of the biosensor, the sample solution is introduced into its insides through inlet (10) wherein the sample fills the space (8). The cover 9 posses a hole having a diameter of 2 mm and forms a discharge port (outlet) 11. With regards to claim 4-6, the claims only require that the spacer have members. The broadest possible reading on this would be a spacer layer that has members formed from an original spacer (fig.4). In Fig. 4, there is a U shaped spacer. The base part of the U would be member 1, the left part of the U would be member 2, and the right part of the U would be member 3. Claim 6 requires that a the second and third members are spaced apart, Fig 4 shows this configuration and further a channel (8) extends between the first, second, and third members. Fig 10, 12 and shows further embodiments of the spacer layer (multiple) and multiple members to create multiple channels have a plurality of outlets.

(10) Response to Argument

Regarding the Appellant's arguments directed to the 112 rejections, the Examiner respectfully disagrees with the Appellant's arguments, specifically citing In re Wakefield in the arguments. The Examiner's focus during examination of claims for compliance with the requirement for definiteness of 35 U.S.C. 112, second paragraph, is whether the claim meets the threshold requirements of clarity and precision, not

whether more suitable language or modes of expression are available. When the Examiner is satisfied that patentable subject matter is disclosed, and it is apparent to the Examiner that the claims are directed to such patentable subject matter, he or she should allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph, would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chem. Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993).

The Examiner maintains that a proper 35 U.S.C 112, second paragraph rejection has been made because the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement. As seen from the numerous examples as seen above in the 112 second paragraph rejection the Examiner has shown that there are numerous problems

associated with the claims of the instant application which provide difficult search and understanding of the instant application. Numerous examples were made to try to aid the Applicant in restructuring the claim language but the attempts failed.

With respect to the rejection under 35 U.S.C 102(b), the Appellant argues, "Independent claims 24, 25, and 26 each recite "individual members." It is noted that the U shaped spacer of Figure 4, in Nankai lacks individual members." The Examiner would like to draw the Appellant's attention to figure 10, where Nankai shows two separate individual spacers 7 and 7' and to figure 12 where Nankai shows three individual members that separate the sample area above the electrodes 41, 42 and 43.

Appellant also argues, "There is certainly no opposing dual directional flow taught or suggested by Nankai et al." This is the first time the Appellant brings up this dual directional flow. The Examiner maintains that in the current pending claims, the inlet accepts a sample and the sample flows to the electrodes where a measurement is made. This flow pattern is a forward flowing setup which is also like what the Appellant says Nankai is. In fact, a search through the instant specification makes no mention of this "opposing dual directional flow." There is no structural difference between the instant claims and that of the prior art of Nankai. The channels employed within the instant application are capillary channels. The principle of capillary channels is that the surface tension created by the diameter of the channel allows for fluid flow to wick or move through the channels in one direction. The Examiner maintains that the claims

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are so unclearly written as seen by all the 112 rejections that the claims had to be interpreted as the Examiner has interpreted them. The prior art of Nankai discloses each and every limitation of the instant claims as interpreted by the Examiner.

(11) Related Proceeding(s) Appendix


No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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